

EPA Reg. No. 62097-42

SciReg, Inc.
Science and Regulatory Consultants

May 12, 2015

Ms. Shaja Joyner
U.S. Environmental Protection Agency
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

Re: Prohexadione Calcium Technical (EPA Reg. No. 62097-42)
Submission of final printed label

Dear Ms. Joyner:

On behalf of Fine Agrochemicals Ltd., attached is one copy of the final printed label, consistent with the Agency's December 17, 2014 Registration Notice, for Prohexadione Calcium Technical.

Should you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosure



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-42	2. EPA Product Manager S. Joyner	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Prohexadione Calcium Technical	PM# 20	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House, Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>12/17/14</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. Per Container	If "Yes" Package wgt.	No. Per Container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container See attached.		5. Location of Label Directions <input type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Frederick T. Smith	Title Agent	Telephone No. (Include Area Code) 703/494-6500
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stampcd)
2. Signature 	3. Title Agent (SciReg, Inc.)	
4. Typed Name Frederick T. Smith	5. Date 5/12/15	

Prohexadione Calcium Technical

Plant growth regulator for manufacturing use only

Active Ingredient: Prohexadione calcium [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate]..... 94.44%
Other Ingredients:..... 5.56%
Total:..... 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg. No. 62097-42

EPA Est. No.

Net Contents:
Batch No.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact the National Poison Control Hotline at 1-800-222-1222 for emergency medical treatment information 24 hours a day, seven days a week.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulating end-use products for apples, grass grown for seed, peanuts and sweet cherry. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration of its end-use products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container only. After partial use, close the container tightly. Store in a secure place that is cool and dry.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Fine Agrochemicals Limited ("FINE") warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, FINE makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of FINE or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as abnormal weather conditions, use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law: 1) FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and 2) FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

© Fine Agrochemicals Limited, Hill End House, Whittington, Worcester, WR5 2RQ,
United Kingdom

Material Sent for Data Extraction

Reg. # 62097-42

Description: New Registration

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 12-17-14

☐ Notification Dated _____

☐ New CSF(s) Dated _____

☐ Other: _____

☐ Decision #: _____

☐ Other Action/Comments: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: R. Kearns

Phone: 305-5611 Division: RD

Date: 12-29-14



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

62097-42

Date of Issuance:

12/17/2014

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Prohexadione Calcium Technical

Name and Address of Registrant (include ZIP Code):

Fine Agrochemicals Limited
Hill End House
Whittington, Worcester
UK WR5 2RQ

E-Mailed to:

Fred Smith, Agent for Fine Agrochemicals Limited
SciReg, Inc.
12733 Directors's Loop
Woodbridge, VA 22192

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

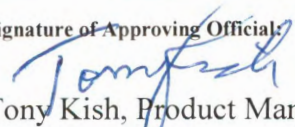
On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:


Tony Kish, Product Manager 22
Fungicide Branch, Registration Division (7505P)

Date:

12/17/2014

2. Your data citations on the data matrix for this product are required to satisfy the data requirements described in the DCI identified below:

- a. Prohexadione calcium GDCl-112600-1313

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above and in the link below, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

http://www.epa.gov/oppsrrd1/contacts_prd.htm

<http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0870-0012>

3. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year GLP study is required to satisfy these data requirements. You have 12 months from the date of registration to provide these data.
4. Make the following label changes before you release the product for shipment:
Revise the EPA Registration Number to read, "EPA Reg. No. 62097-42."
5. Submit one copy of the final printed label before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated January 15, 2014

If you have any questions, please contact me at (703) 308-9443 or kish.tony@epa.gov.

Tony Kish, Product Manager 22

Fungicide Branch
Registration Division (7505P)

Enclosure-approved label

Prohexadione Calcium Technical

Plant growth regulator for manufacturing use only

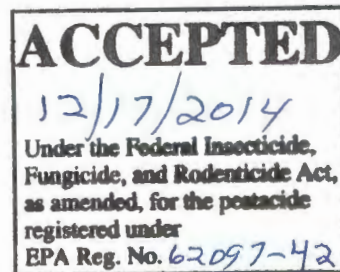
Active Ingredient: Prohexadione calcium [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate]94.44%
Other Ingredients:5.56%
Total:100.00%

KEEP OUT OF REACH OF CHILDREN
CAUTION

EPA Reg. No. 62097-

EPA Est. No.

Net Contents:
Batch No.



FIRST AID	
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PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product into sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

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PESTICIDE STORAGE: Store in original container only. After partial use, close the container tightly. Store in a secure place that is cool and dry.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING: Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Fine Agrochemicals Limited ("FINE") warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, FINE makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of FINE or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as abnormal weather conditions, use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law: 1) FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and 2) FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

© Fine Agrochemicals Limited, Hill End House, Whittington, Worcester, WR5 2RQ,
United Kingdom



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: 418727; **FILE SYMBOL No.:** 62097-UE; **PRODUCT NAME:** Prohexadione Calcium Technical; **DECISION No.:** 487223; **PC Code(s):** 112600; **ACTION CODE:** R334; **FOOD Use:** Yes

DATE: December 16, 2014

SUBJECT: Product Chemistry Review of "Prohexadione Calcium Technical"

FROM: Debra Rate, Ph.D.
Biologist
Registration Division (7505P)

Debra N. Rate
JCR

TO: Rose Kearns / Tony Kish, RM 24
Fungicide Branch / RD (7505P)

REGISTRANT: Fine Agrochemicals, Ltd.

USE: Fungicide

FOOD USE: Yes ☒ No ☐

MRID Numbers: 49298401 and 49298402

INTRODUCTION:

Fine Agrochemicals, Ltd., has submitted an application for a new "Me-too" registration for a technical product with the active ingredient, prohexadione calcium. The registrant has submitted a CSF for basic formulation (dated 01/15/2014) and Group A product chemistry data with MRID Nos. 49298401, 49298401, and 49526801. The registrant is claiming substantial similarity to EPA Reg. 7969-190, and has cited the Group B product chemistry. CITAB (Chemistry) has been asked to evaluate and determine the acceptability of the proposed basic CSF (dated 01/15/2014), the supporting product chemistry data and determine similarity to the cited product.

SUMMARY OF FINDINGS:

1. The findings for Group A guideline data were as follows:

830.1550 (product identity & composition): The registrant has submitted a CSF for basic formulation (dated 01/15/2014). The product chemistry data corresponding to this guideline submitted on the CSF satisfy the data requirements of 40CFR§158.320. The nominal concentration 94.44% for active ingredient (prohexadione calcium) concurs with the product label claim nominal concentration of 94.44%. [MRID 49298401].

830.1600 (description of materials used to produce the product): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§ 158.325. The registrant has submitted the MSDS's for all the starting materials used to produce the prohexadione calcium technical product [MRID No. 49298401].

830.1620 (description of production process): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.330. The prohexadione calcium is produced in a [REDACTED]. The details of the production process have been provided by the registrant [MRID No. 49298401 and supplemental information provided to reviewer].

830.1670 (discussion on the formation of impurities): The product chemistry data submitted corresponding to this guideline satisfy the data requirements for 40CFR§158.340. The registrant has [REDACTED] impurities on the proposed basic CSF dated 01/15/2014 which were detected at the concentrations of >0.1%. [MRID No. 49298401 and supplemental information provided to reviewer].

830.1700 (preliminary analysis): The product chemistry data submitted corresponding to this guideline support the claims on the basic CSF (dated 01/15/2014) and satisfy the data requirements of 40CFR§158.345. Five lots of the test substance were analyzed to determine the level of the active ingredient and impurity profile of the technical product. The study was conducted at Intertek Pharmaceutical Services of Manchester, Manchester, UK. The content of the active ingredient was determined by external standard calibration using HPLC/UV (UV at 270 nm). The method was previously validated. See the Confidential Appendix for details on the impurities analysis [MRID No. 49298402 and 49526801].

830.1750 (certified limits): The product chemistry data submitted corresponding to this guideline satisfy the data requirements of 40CFR§158.350. The certified limits of the active ingredient are in accordance with Agency standards and the certified limits for the associated impurities are based on the five batch analysis [MRID No. 49298402].

830.1800 (enforcement analytical method): The product chemistry data submitted corresponding to this guideline satisfy the requirements of 40CFR§158.355. The content of the active ingredient was determined by using a HPLC/UV validated method and quantified using an external standard technique. The analytical method was validated for precision, accuracy and linearity [MRID No. 49298402 and 49526801].

2. The 830 series Group B guideline data (physical-chemical properties) were cited based on the "substantially similar" claim to EPA Reg. No. 7969-190 to satisfy the data requirements of 40CFR§158.310(e). All Group B guideline studies were addressed on the data matrix with the exception of the guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) [See Data Matrix for cited MRID Nos.].

CONCLUSIONS:

The CITAB (Chemistry) has reviewed the product chemistry data submitted for Prohexadione Calcium Technical to support the proposed basic CSF (dated 01/15/2014) and has evaluated the similarity claim. The CITAB (Chemistry) has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A are acceptable.
2. The proposed CSF for basic formulation (dated 01/15/2014) is acceptable.
3. With respect to product chemistry (physical properties, impurity profiles, etc.), CITAB (Chemistry) concludes that the proposed product can be considered similar to the cited product, 7969-190.
4. Based on the similarity, the product chemistry data cited for guideline 830 Series Group B are acceptable, with the exception of the guidelines 830.6317 (Storage Stability) and 830.6320 (Corrosion Characteristics). The results for these studies must be submitted to the Agency upon completion.

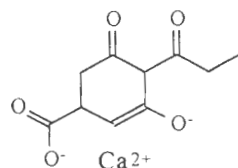
DP BARCODE No.: 418727, **FILE SYMBOL No.:** 62097-UE; **PRODUCT NAME:** Prohexadione Calcium Technical; **DECISION No.:** 487223; **PC Code(s):** 112600; **ACTION CODE:** R334; **FOOD Use:** Yes

830.1550. Product identity & composition: (MRID No. 49298401)\

Trade Name:	Prohexadione Calcium Technical
IUPAC Name:	Calcium 1-(4-carboxy-2, 6-dioxocyclohexylidene)propan-1-olate
Common Name:	Prohexadione-Calcium
CAS Number:	127277-53-6
PC Code:	112600

Empirical Formula:	$C_{10}H_{10}O_5Ca$
Molecular Mass:	250.26

Structural Formula:



$C_{10}H_{10}CaO_5$
250.27

DP BARCODE No.: 418727; FILE SYMBOL No.: 62097-UE; PRODUCT NAME: Prohexadione Calcium Technical; DECISION No.: 487223; PC Code(s): 112600; ACTION CODE: R334; FOOD Use: Yes

Group A Data

Table 1. Group A Product Chemistry Data for Prohexadione Calcium Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	49298401	A	Submitted basic CSF (dated 01/15/2014) with nominal concentration of 94.44% for the active ingredient.
830.1600	Description of materials used to produce the product	49298401	A	Submitted the MSDS's for all the starting materials used in the synthesis of Prohexadione Calcium Technical [REDACTED]
830.1620	Description of production process	49298401 (additional notes provided to reviewer)	A	The prohexadione calcium technical product is produced in a [REDACTED]. The manufacturing process has been described in detail with reaction conditions. [REDACTED] [REDACTED] [REDACTED]
830.1670	Discussion of formation of impurities	49298401	A	The registrant discussed the formation of impurities and confirmed that there were no impurities of toxicological concern. [REDACTED] impurities have been listed in the CSF present at levels of >0.1%. There were no other impurities identified during the analysis at levels >0.1%.
830.1700	Preliminary analysis	49298402 49526801	A	The HPLC/UV (270 nm, external standard) method has been used for the determination, identification and quantitation of the active ingredient, prohexadione calcium. The associated impurities were determined by HPLC/UV (270 nm), as well as other techniques described in the review. The details of the validated methods have been submitted.
830.1750	Certified limits	49298402	A	The proposed limits for the active ingredient and the impurities are based on five batch analysis.
830.1800	Enforcement analytical method	49298402 49526801	A	The HPLC/UV (270 nm) method was used for the determination of the active ingredient contents. The external standard quantification technique was used. The method was validated for precision, linearity and accuracy.
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress; U = Up-grade (additional information required);				

830 Series Group B (Physical-Chemical properties)

Data for "substantially similar" product, EPA Reg. No. 7969-190, were cited to fulfill these guidelines. Citations for these guidelines are acceptable, with the exception of the 1 year storage stability (830.6317) and corrosion characteristics (830.6320) studies.

830.1800 (enforcement analytical method) (MRID N. 49298402 and 49526801)

See the data on guideline 830.1700 (preliminary analysis)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 18-NOV-2014

Subject: Prohexadione Calcium; Review of Data Matrix for Me-Too Product.

PC Code:	112600	DP Barcode:	D418732
Decision No.:	487223	Registration Nos.:	62097-UE, 7969-190
Petition No.:	None	Regulatory Actions:	New product
Risk Assessment Type:	Not Applicable	Case No.:	7030
TXR No.:	NA	CAS No.:	127277-53-6
MRID No.:	None	40 CFR:	§180.547

From: William D. Wassell, Chemist
Anwar Y. Dunbar, Ph.D., Pharmacologist
Risk Assessment Branch 1 (RAB1)
Health Effects Division (HED, 7509P)

Through: Charles W. Smith III, Branch Chief
George F. Kramer, Ph.D., Senior Chemist
RAB1/HED (7509P)

To: Shaja Joyner/Rosemary Kearns, RM-24
Fungicide Branch (FB)
Registration Division (RD, 7505P)

Introduction

HED has been asked to review the data matrix, verify each matrix listing as correct, and weather any listings are missing from the matrix submitted to support a new product that claims to be similar to prohexadione calcium manufacturing-use product (EPA Reg. No. 7969-160).

Detailed Considerations:

Prohexadione calcium (calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate) is a plant growth regulator that acts by inhibiting the biosynthesis of gibberellins, resulting in a decrease in cell elongation and a slowing of cell growth. Prohexadione calcium is registered for use on agricultural and nonagricultural areas. The agricultural uses of prohexadione calcium include foliar applications to pome fruit, peanut, grass, and cherries. Tolerances are established for residues of prohexadione calcium in/on these crops at 0.10 to 3.5 ppm (40 CFR §180.547). There are also tolerances established for secondary residues of prohexadione calcium in/on livestock commodities.

Fine Agrochemicals Ltd. has proposed registration of a new formulation of the active ingredient (ai) prohexadione calcium formulation for manufacturing use only. The new product is referred to as Prohexadione Calcium Technical (EPA Reg. No. 62097-UE) and contains 94.44% ai by weight. The currently registered prohexadione calcium product contains 94.0% ai by weight.

HED has examined the data matrix in relationship to the residue chemistry and toxicology data requirements and found it to be accurate; however, there are two additional studies that should be cited. The additional studies are:

48106701 Lehmann, A.; Mackenroth, C. (2005) Validation of the Analytical Method 564/0: Method for the Determination of Prohexadione-Ca in Plant and Animal Matrices. Project Number: 2005/1007581/US/OCR, EU/134609, 2005/1007581. Unpublished study prepared by BASF Aktiengesellschaft. 65 p.

45190501 Jordan, E. (2000) Response to PP#8F4941: Evaluation of Residue Chemistry Data to Support Permanent Tolerances for Prohexadione-Calcium on Peanuts, Pome Fruits, and Cattle, Meat Byproducts (Kidney): Lab Project Number: 2000/5213. Unpublished study prepared by BASF Corporation. 9 p.

Regarding the waiver request for the guideline Immunotoxicity study, HED's Hazard Science and Policy Council (HASPOC) met on November 7, 2013 (TXR# 00576827) to evaluate the need for an immunotoxicity study for prohexadione calcium. The HASPOC concluded that based on a weight-of-evidence approach considering all hazard and exposure data for prohexadione calcium, that an immunotoxicity study was not required.

SciReg, Inc.
Science and Regulatory Consultants

December 12, 2014

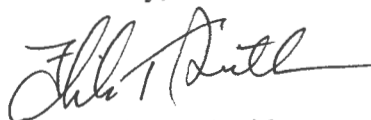
Mr. Tony Kish
Document Processing Desk
Office of Pesticides Programs (7504P)
U.S Environmental Protection Agency
Room S-9400, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202

Re: Prohexadione Calcium Technical (EPA File Symbol 62097-UE)

Dear Mr. Kish:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is submitting the method validation for Prohexadione Calcium Technical (EPA File Symbol 62097-UE). If you have any questions, please let me know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Fine Agrochemicals Ltd., Hill End House, Whittington, Worcester WR5 2RQ, UK Phone 011 44 1905 361800	EPA Registration Number/File Symbol 62097-0E
Active Ingredient(s) and/or representative test compound(s) Prohexadione calcium (PC Code 112600)	Date 12/12/14
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food; terrestrial non-food	Product Name Kudos™ 27.5 WDG

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 12/12/14	Typed or Printed Name and Title Frederick T. Smith, Agent (SciReg, Inc.)
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401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date <u>12/12/14</u>	EPA Reg No./File Symbol <u>62097-</u>	Page <u>1</u> of <u>9</u>
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Kudos™ 27.5 WDG	

Ingredient Prohexadione-calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition	49298801	Fine Agrochemicals Ltd.	OWN	
830.1600	Desc. of mat. used to produce the product	49298801	Fine Agrochemicals Ltd.	OWN	
830.1650	Desc. of formulation process	49298801	Fine Agrochemicals Ltd.	OWN	
830.1670	Discussion of formation of impurities	49298801	Fine Agrochemicals Ltd.	OWN	
830.1750	Certified limits	49298801	Fine Agrochemicals Ltd.	OWN	
830.1800	Enforcement analytical method	49298402	Fine Agrochemicals Ltd.	OWN	
830.6302-830.7520	Physical-chemical properties summary	49298802	Fine Agrochemicals Ltd.	OWN	
830.6302	Color	49298803	Fine Agrochemicals Ltd.	OWN	
830.6303	Physical state	49298803	Fine Agrochemicals Ltd.	OWN	
830.6304	Odor	49298803	Fine Agrochemicals Ltd.	OWN	
830.6314	Oxidation/reduction	49298803	Fine Agrochemicals Ltd.	OWN	
830.7000	pH	49298803	Fine Agrochemicals Ltd.	OWN	
830.7300	Density	49298803	Fine Agrochemicals Ltd.	OWN	
830.7520	Particle size distribution	49298803	Fine Agrochemicals Ltd.	OWN	

Signature

Name and Title
Frederick T. Smith, Agent (SciReg, Inc.)

Date

12/12/14



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Kudos™ 27.5 WDG	

Ingredient Prohexadione-calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	

Signature <u>Frederick T. Smith</u>	Name and Title Frederick T. Smith, Agent (SciReg, Inc.)	Date <u>12/12/14</u>
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Date 12/12/14	EPA Reg No./File Symbol 62097-	Page 2 of 9
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Product

Kudos™ 27.5 WDG

Ingredient	Prohexadione calcium
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[illegible]

Signature _____

H. T. Mull

Name and Title

Frederick T. Smith, Agent (SciReg, Inc.)

Date _____

12/12/14



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Date <u>12/12/14</u>	EPA Reg No./File Symbol <u>62097-</u>	Page <u>2</u> of <u>9</u>
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EPA Reg No./File Symbol	62097-	Page	2	of	5
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Kudos™ 27.5 WDG

[illegible]

Name and Title
Frederick T. Smith, Agent (SciReg, Inc.)

Date
12/12/14



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione-Calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition	49298401	Fine Agrochemicals Ltd.	OWN	
830.1600	Desc. of mat. used to produce the product	49298401	Fine Agrochemicals Ltd.	OWN	
830.1620	Desc. of production process	49298401	Fine Agrochemicals Ltd.	OWN	
830.1670	Discussion of formation of impurities	49298401	Fine Agrochemicals Ltd.	OWN	
830.1700	Preliminary analysis	49298402	Fine Agrochemicals Ltd.	OWN	
830.1750	Certified limits	49298401	Fine Agrochemicals Ltd.	OWN	
830.1800	Enforcement analytical method	49298402	Fine Agrochemicals Ltd.	OWN	
830.6302	Color	44457704	BASF Corporation	OLD	
830.6303	Physical state	44457705	BASF Corporation	OLD	
830.6304	Odor	44457706	BASF Corporation	OLD	
830.6313	Stability	44457716	BASF Corporation	OLD	
830.6314	Oxidation/reduction	44457717	BASF Corporation	OLD	
830.6316	Explosibility	44457717	BASF Corporation	OLD	
830.7000	pH	44457715	BASF Corporation	OLD	
830.7200	Melting point	44457707	BASF Corporation	OLD	
830.7300	Density	44457708	BASF Corporation	OLD	
830.7370	Dissociation constant	44457713	BASF Corporation	OLD	
830.7550	Octanol/water partition coefficient	44457714	BASF Corporation	OLD	
830.7840	Solubility	44457709 44457710 44457711	BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD	
830.7950	Vapor Pressure	44457712	BASF Corporation	OLD	
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>	

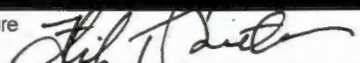


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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione-Calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			Fine Agrochemicals Ltd.	OWN	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
		Signature <u></u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)	

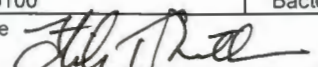


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Date <u>12/12/14</u>		EPA Reg No./File Symbol	62097-	Page 4 of 9	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity	44457742	BASF Corporation	OLD	
870.1200	Acute dermal toxicity	44457743	BASF Corporation	OLD	
870.1300	Acute inhalation toxicity	44457744	BASF Corporation	OLD	
870.2400	Primary eye irritation	44457745	BASF Corporation	OLD	
870.2500	Primary dermal irritation	44457746	BASF Corporation	OLD	
870.2600	Dermal sensitization	44457747	BASF Corporation	OLD	
870.6100	Acute neurotoxicity - rat	44457748	BASF Corporation	OLD	
870.6200	90-Day neurotoxicity - rat	44457753	BASF Corporation	OLD	
870.3100	90-Day Oral - rodent	44457749	BASF Corporation	OLD	
		44457750	BASF Corporation	OLD	
		44499902	BASF Corporation	OLD	
870.3150	90-Day Oral - non-rodent	44457751	BASF Corporation	OLD	
		44457752	BASF Corporation	OLD	
870.3200	21/28-day dermal TGAI	45430301	BASF Corporation	PAY	
870.4100	Chronic - rodent	44457754	BASF Corporation	OLD	
870.4100	Chronic - non-rodent	44457751	BASF Corporation	OLD	
		44457755	BASF Corporation	OLD	
870.4200	Oncogenicity - rat	44457754	BASF Corporation	OLD	
870.4200	Oncogenicity - mice	44457756	BASF Corporation	OLD	
870.3700	Developmental toxicity - rat	44457757	BASF Corporation	OLD	
		44457758	BASF Corporation	OLD	
		44457759	BASF Corporation	OLD	
		44457760	BASF Corporation	OLD	
		44457761	BASF Corporation	OLD	
870.3700	Developmental toxicity - rabbit	44457762	BASF Corporation	OLD	
		44457763	BASF Corporation	OLD	
		44457764	BASF Corporation	OLD	
870.3800	Reproduction, 2-generation	44457764	BASF Corporation	OLD	
870.5100	Bacterial reverse mutation assay	44457765	BASF Corporation	OLD	
Signature 			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date 12/12/14



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Prohexadione Calcium Technical	

Ingredient Prohexadione calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	

Signature <u>Frederick T. Smith</u>	Name and Title Frederick T. Smith, Agent (SciReg, Inc.)	Date <u>12/12/14</u>
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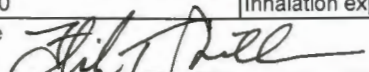


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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5300 870.5375	<i>In vitro</i> mammalian cell assay	44457768 44499903 44499904	BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD	
870.5385 870.5395	<i>In vivo</i> cytogenetics	44457767 44457769	BASF Corporation BASF Corporation	OLD OLD	
870.7485	Metabolism and pharmacokinetics	44457770 44457771 44457772 44457773	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
870.7800	Immunotoxicity	49298403	Fine Agrochemicals Ltd.	OWN	
835.4200 835.4300 850.1010 870.3200 875.2200	Toxicology, Terrestrial and Aquatic Nontarget Organism, Environmental Fate, and Post-Application Exposure Waiver Requests	49298404	Fine Agrochemicals Ltd.	OWN	
875.1100	Dermal outdoor exposure	CITE-ALL	Agricultural Handler Exposure (AHETF) Agricultural Reentry Task Force (ARTF) Outdoor Residential Exposure Task Force (ORETF)	PER PER PER	
875.1300	Inhalation outdoor exposure	CITE-ALL	AHETF ARTF ORETF	PER PER PER	
875.1600	Data reporting and calculations	CITE-ALL	AHETF ARTF ORETF	PER PER PER	
875.2100	Dislodgeable foliar residue	49270502	BASF Corporation	PAY	
875.2400	Dermal exposure	CITE-ALL	ARTF	PER	
875.2500	Inhalation exposure	CITE-ALL	ARTF	PER	
Signature 			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			Fine Agrochemicals Ltd.	OWN	
			Agricultural Handler Exposure (AHETF)	PER	
			Agricultural Reentry Task Force (ARTF)	PER	
			Outdoor Residential Exposure Task Force (ORETF)	PER	
			AHETF	PER	
			ARTF	PER	
			ORETF	PER	
			AHETF	PER	
			ARTF	PER	
			ORETF	PER	
			BASF Corporation	PAY	
ARTF	PER				
ARTF	PER				
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>	




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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Informative Summary: Toxicological Profile, Aggregate Risk Assessment and Determination of Safety for Prohexadione Calcium Tolerances on Peanuts	44457811	BASF Corporation	OLD	
835.2120	Hydrolysis	44457782	BASF Corporation	OLD	
835.2240	Photodegradation in water	44457783	BASF Corporation	OLD	
835.2410	Photodegradation in soil	44457784	BASF Corporation	OLD	
835.4100	Aerobic soil metabolism	44457785	BASF Corporation	OLD	
835.4400	Anaerobic aquatic metabolism	44457786	BASF Corporation	OLD	
835.1230 835.1240	Leaching/adsorption/desorption	44457787 44457788 44457789 44457790	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
835.6100	Terrestrial field dissipation	44457791 44725213 44725214 44725215	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
Signature <u></u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date <u>12/12/14</u>		EPA Reg No./File Symbol <u>62097-</u>		Page <u>6</u> of <u>9</u>	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian acute oral - passerine	49270501	BASF Corporation	PAY	
850.2100	Avian acute oral - quail or duck	44457723 44457724	BASF Corporation BASF Corporation	OLD OLD	
850.2200	Avian dietary toxicity - quail	44457725	BASF Corporation	OLD	
850.2200	Avian dietary toxicity - duck	44457726	BASF Corporation	OLD	
850.2300	Avian reproduction - quail	44457727	BASF Corporation	OLD	
850.2300	Avian reproduction - duck	44457728	BASF Corporation	OLD	
850.1075	Freshwater fish LC50 - cold water species (TGAI)	44457730	BASF Corporation	OLD	
850.1075	Freshwater fish LC50 - warm water species (TGAI)	44457729	BASF Corporation	OLD	
850.1010	Freshwater invertebrate LC50 - (TGAI)	44457731	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - fish (TGAI)	44457732	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - mollusk (TGAI)	44457733	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - shrimp (TGAI)	44457734	BASF Corporation	OLD	
850.1300	Aquatic invertebrate life cycle - freshwater	CITE-ALL	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600); MRID No. not yet assigned.
850.1400	Fish early life stage - freshwater	CITE-ALL	BASF Corporation	PAY	
850.3020	Honey bee acute contact LD50	44457781	BASF Corporation	OLD	
850.4100	Seedling emergence, Tier I	CITE-ALL	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600); DCI study due date, 1/31/15.
850.4150	Vegetative vigor, Tier I	CITE-ALL	BASF Corporation	PAY	
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>




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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600); MRID No. not yet assigned.
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600); DCI study due date, 1/31/15.
			BASF Corporation	PAY	
Signature <u></u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Prohexadione Calcium Technical	

Ingredient Prohexadione calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400 850.5400	Aquatic plant growth, Tier I	44457776 44457777 44457778 44457779 44457780	BASF Corporation BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD OLD	
860.1300	Nature of residue - apple	44425216	BASF Corporation	OLD	
860.1300	Nature of residue - hen	44457794	BASF Corporation	OLD	
860.1300	Nature of residue - goat	44457801	BASF Corporation	OLD	
860.1300	Metabolism of (carbon 14) - Prohexadione Calcium in Peanut	44457793	BASF Corporation	OLD	
860.1340	Independent method validation - animal tissues, milk, and apple commodities	44457804	BASF Corporation	OLD	
860.1340	Residue analytical method - animal tissues (liver, kidney, fat, and muscle), milk, and apple commodities	44457805	BASF Corporation	OLD	
860.1340	Residue analytical method-plants	44725217	BASF Corporation	OLD	
860.1340	Independent method validation of Analytical Method for Peanuts	44457803	BASF Corporation	OLD	
860.1340	Method for Determination of Prohexadione Residues in Peanut RAC (Nutmeat and Hay), and Peanut Process Fractions (Meal and Animal Matrices	44457806	BASF Corporation	OLD	
860.1340	Independent Laboratory Validation for the Determination of Prohexadione-Ca in Plant and Animal Matrices	48106702	BASF Corporation	PAY	

Signature

Name and Title
Frederick T. Smith, Agent (SciReg, Inc.)

Date

12/12/14



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Prohexadione Calcium Technical	

Ingredient Prohexadione calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	

Signature <u>Frederick T. Smith</u>	Name and Title Frederick T. Smith, Agent (SciReg, Inc.)	Date <u>12/12/14</u>
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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom			Product Prohexadione Calcium Technical		
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1340	Method validation	48106701	BASF Corporation	PAY	
860.1360	Multiresidue method	44457802	BASF Corporation	OLD	
860.1380	Storage stability - apples	45067901	BASF Corporation	PAY	
860.1380	Storage stability - peanuts	44457807	BASF Corporation	OLD	
860.1380	Storage stability - peanuts	44725218	BASF Corporation	OLD	
860.1480	Magnitude of residue - cow	44457809	BASF Corporation	OLD	
860.1500	Magnitude of residue - apple	44725220	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanuts	44457808	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanut process fractions	44457810	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanuts	44725219	BASF Corporation	OLD	
860.1500	Magnitude of residues in cool season grasses grown for seed	45136201	K.I. Chemicals USA Inc.	PAY	
860.1500	Magnitude of residue in sweet cherry	48106703	BASF Corporation	PAY	
860.1520	Magnitude of residue - processed apple fractions	44725222	BASF Corporation	OLD	
	Magnitude of residue - overview	44725223	BASF Corporation	OLD	
860.1850	Confined rotational crop	44457792	BASF Corporation	OLD	
	Informative Summary: Toxicological Profile Aggregate Risk Assessment and Determination of Safety for Prohexadione Calcium Tolerances on Peanuts and Pome Fruit	44725224	BASF Corporation	OLD	
	Response to petition	45190501	BASF Corporation	PAY	
840.1100	Droplet size spectrum	CITE-ALL	Spray Drift Task Force	PAY	
840.1200	Drift field evaluation	CITE-ALL	Spray Drift Task Force	PAY	
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			K.I. Chemicals USA Inc.	PAY	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			Spray Drift Task Force	PAY	
			Spray Drift Task Force	PAY	
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/12/14</u>	

Kish, Tony

From: Kish, Tony
Sent: Thursday, December 04, 2014 5:57 PM
To: Shah, Pv; Mathur, Shyam
Cc: Kearns, Rosemary
Subject: Prohexadione calcium - end use product- 62097-UR--one more question

Below is mentioned the review for the unregistered MP we need, but the associated review for the EP which uses this pending MP (DP418683; pc code 112600)) states they need the missing enforcement method validation data to confirm precision, linearity, and accuracy for the nominal concentration of the EP formula. The registrant questioned this need and mentioned the 5-batch data so what should we tell him?

Many Thanks,
Tony Kish
Product Manager, Team 22
Fungicides Branch; Registration Division
703-308-9443

From: Kish, Tony
Sent: Thursday, December 04, 2014 5:24 PM
To: Shah, Pv; Mathur, Shyam
Cc: Kearns, Rosemary
Subject: DP418727- prohexadione calcium technical- 62097-UE

Hi Pv/Shyam- OPPIN indicates this review is pending but we need it next week by wed 12/10/14. Can this review be completed by then (or maybe it's done but not logged out)?

Many Thanks,
Tony Kish
Product Manager, Team 22
Fungicides Branch; Registration Division
703-308-9443

Kish, Tony

From: Kish, Tony
Sent: Thursday, December 04, 2014 5:24 PM
To: Shah, Pv; Mathur, Shyam
Cc: Kearns, Rosemary
Subject: DP418727- prohexadione calcium technical- 62097-UE

Tracking:	Recipient	Delivery
	Shah, Pv	Delivered: 12/4/2014 5:24 PM
	Mathur, Shyam	Delivered: 12/4/2014 5:24 PM
	Kearns, Rosemary	Delivered: 12/4/2014 5:24 PM

Hi Pv/Shyam- OPPIN indicates this review is pending but we need it next week by wed 12/10/14. Can this review be completed by then (or maybe it's done but not logged out)?

Many Thanks,
Tony Kish
Product Manager, Team 22
Fungicides Branch; Registration Division
703-308-9443

Prohexadione MP
62097-UE

Fungicide Branch Assignment Sheet

Related to 62097-UR(EP)

Date Delivered to PM

3/11/14
(date & initial) DM

Mary Waller
PM 21

Tony Kish
PM 22

Acting PM 20

Risk Managers

Tamue

Erin

Heather

Rose

Dominic

Summer

Shaunta

Bob

Banza

Comments to Summer

Comments to Risk Manager Ream 49298401 and -402 to problem.
No acute Ream needed see Sinclair Review. Data matrix Review
is VIP! Ream to HED with MRID 49298403, meeting
minutes 12/11/13, cover letter, label, matrix. Ask them to
verify each and every matrix listing as correct and whether
any listings are missing. EPED Ream with some info

Date to Summer TK 3/12/14 and Request except do
(date & initial) not include 49298403.

* Screen Reviews due dates in Ream 2 weeks prior to
Date to Risk Manager (date stamp & initial area below) actual due date.

* Also include MRID 49298404 with HED/EPED Ream



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WASHINGTON, D.C. 20460

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Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Fine Agrochemicals Ltd., Hill End House, Whittington, Worcester WR5 2RQ, UK Phone 011 44 1905 361800	EPA Registration Number/File Symbol 62097-
Active Ingredient(s) and/or representative test compounds(s) Prohexadione calcium	Date 12/5/14
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food; terrestrial non-food	Product Name Prohexadione Calcium Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☒ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

12/5/14

Typed or Printed Name and Title

Frederick T. Smith, Agent (SciReg, Inc.)




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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition	49298401	Fine Agrochemicals Ltd	OWN	
830.1600	Desc. of mat. used to produce the product	49298401	Fine Agrochemicals Ltd	OWN	
830.1620	Desc. of production process	49298401	Fine Agrochemicals Ltd.	OWN	
830.1670	Discussion of formation of impurities	49298401	Fine Agrochemicals Ltd.	OWN	
830.1700	Preliminary analysis	49298402	Fine Agrochemicals Ltd.	OWN	
830.1750	Certified limits	49298401	Fine Agrochemicals Ltd.	OWN	
830.1800	Enforcement analytical method	49298402	Fine Agrochemicals Ltd.	OWN	
830.6302	Color	44457704	BASF Corporation	OLD	
830.6303	Physical state	44457705	BASF Corporation	OLD	
830.6304	Odor	44457706	BASF Corporation	OLD	
830.6313	Stability	44457716	BASF Corporation	OLD	
830.6314	Oxidation/reduction	44457717	BASF Corporation	OLD	
830.6316	Explosibility	44457717	BASF Corporation	OLD	
830.7000	pH	44457715	BASF Corporation	OLD	
830.7200	Melting point	44457707	BASF Corporation	OLD	
830.7300	Density	44457708	BASF Corporation	OLD	
830.7370	Dissociation constant	44457713	BASF Corporation	OLD	
830.7550	Octanol/water partition coefficient	44457714	BASF Corporation	OLD	
830.7840	Solubility	44457709 44457710 44457711	BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD	
830.7950	Vapor Pressure	44457712	BASF Corporation	OLD	
Signature 		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>	



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Ingredient Prohexadione-Calcium						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
			Fine Agrochemicals Ltd	OWN		
			Fine Agrochemicals Ltd	OWN		
			Fine Agrochemicals Ltd	OWN		
			Fine Agrochemicals Ltd	OWN		
			Fine Agrochemicals Ltd	OWN		
			Fine Agrochemicals Ltd	OWN		
			Fine Agrochemicals Ltd	OWN		
			BASF Corporation	OLD		
			BASF Corporation	OLD		
			BASF Corporation	OLD		
			BASF Corporation	OLD		
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			BASF Corporation	OLD		
			BASF Corporation	OLD		
			BASF Corporation	OLD		
			Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
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DATA MATRIX

Date <u>12/5/14</u>		EPA Reg No./File Symbol	62097-	Page 2 of 7	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity	44457742	BASF Corporation	OLD	
870.1200	Acute dermal toxicity	44457743	BASF Corporation	OLD	
870.1300	Acute inhalation toxicity	44457744	BASF Corporation	OLD	
870.2400	Primary eye irritation	44457745	BASF Corporation	OLD	
870.2500	Primary dermal irritation	44457746	BASF Corporation	OLD	
870.2600	Dermal sensitization	44457747	BASF Corporation	OLD	
870.6100	Acute neurotoxicity - rat	44457748	BASF Corporation	OLD	
870.6200	90-Day neurotoxicity - rat	44457753	BASF Corporation	OLD	
870.3100	90-Day Oral - rodent	44457749 44457750 44499902	BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD	
870.3150	90-Day Oral - non-rodent	44457751 44457752	BASF Corporation BASF Corporation	OLD OLD	
870.3200	21/28-day dermal TGA1	45430301	BASF Corporation	PAY	
870.4100	Chronic - rodent	44457754	BASF Corporation	OLD	
870.4100	Chronic - non-rodent	44457751 44457755	BASF Corporation BASF Corporation	OLD OLD	
870.4200	Oncogenicity - rat	44457754	BASF Corporation	OLD	
870.4200	Oncogenicity - mice	44457756	BASF Corporation	OLD	
870.3700	Developmental toxicity - rat	44457757 44457758	BASF Corporation BASF Corporation	OLD OLD	
870.3700	Developmental toxicity - rabbit	44457759 44457760 44457761 44457762	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
870.3800	Reproduction, 2-generation	44457763 44457764	BASF Corporation BASF Corporation	OLD OLD	
870.5100	Bacterial reverse mutation assay	44457765	BASF Corporation	OLD	
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whitlington Worcester WR5 2RQ United Kingdom	Product Prohexadione Calcium Technical	

Ingredient Prohexadione calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>

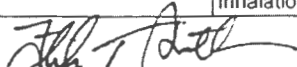


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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5300	<i>In vitro</i> mammalian cell assay	44457768	BASF Corporation	OLD	
870.5375		44499903	BASF Corporation	OLD	
		44499904	BASF Corporation	OLD	
870.5385	<i>In vivo</i> cytogenetics	44457767	BASF Corporation	OLD	
870.5395		44457769	BASF Corporation	OLD	
870.7485	Metabolism and pharmacokinetics	44457770	BASF Corporation	OLD	
		44457771	BASF Corporation	OLD	
		44457772	BASF Corporation	OLD	
		44457773	BASF Corporation	OLD	
870.7800	Immunotoxicity	49298403	Fine Agrochemicals Ltd	OWN	
835.4200	Toxicology, Terrestrial and Aquatic Nontarget Organism, Environmental Fate, and Post-Application Exposure Waiver Requests	49298404	Fine Agrochemicals Ltd	OWN	
835.4300					
850.1010					
870.3200					
875.2200					
875.1100	Dermal outdoor exposure	CITE-ALL	Agricultural Handler Exposure (AHETF) Agricultural Reentry Task Force (ARTF) Outdoor Residential Exposure Task Force (ORETF)	PER PER PER	
875.1300	Inhalation outdoor exposure	CITE-ALL	AHETF ARTF ORETF	PER PER PER	
875.1600	Data reporting and calculations	CITE-ALL	AHETF ARTF ORETF	PER PER PER	
875.2100	Dislodgeable foliar residue	CITE-ALL	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF.
875.2400	Dermal exposure	CITE-ALL	ARTF	PER	
875.2500	Inhalation exposure	CITE-ALL	ARTF	PER	
Signature 			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date 12/5/14



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			Fine Agrochemicals Ltd.	OWN	
			Agricultural Handler Exposure (AHETF)	PER PER PER	
			Agricultural Reentry Task Force (ARTF)		
			Outdoor Residential Exposure Task Force (ORETF)		
			AHETF	PER	
			ARTF	PER	
			ORETF	PER	
			AHETF	PER	
			ARTF	PER	
			ORETF	PER	
	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF.		
	ARTF	PER			
	ARTF	PER			
Signature <i>Frederick T. Smith</i>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <i>12/5/14</i>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient <u>Prohexadione calcium</u>					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Informative Summary: Toxicological Profile, Aggregate Risk Assessment and Determination of Safety for Prohexadione Calcium Tolerances on Peanuts	44457811	BASF Corporation	OLD	
835.2120	Hydrolysis	44457782	BASF Corporation	OLD	
835.2240	Photodegradation in water	44457783	BASF Corporation	OLD	
835.2410	Photodegradation in soil	44457784	BASF Corporation	OLD	
835.4100	Aerobic soil metabolism	44457785	BASF Corporation	OLD	
835.4400	Anaerobic aquatic metabolism	44457786	BASF Corporation	OLD	
835.1230 835.1240	Leaching/adsorption/desorption	44457787 44457788 44457789 44457790	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
835.6100	Terrestrial field dissipation	44457791 44725213 44725214 44725215	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
Signature <i>Frederick T. Smith</i>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <i>12/5/14</i>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian acute oral - passerine	CITE-ALL	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF.
850.2100	Avian acute oral - quail or duck	44457723 44457724	BASF Corporation BASF Corporation	OLD OLD	
850.2200	Avian dietary toxicity - quail	44457725	BASF Corporation	OLD	
850.2200	Avian dietary toxicity - duck	44457726	BASF Corporation	OLD	
850.2300	Avian reproduction - quail	44457727	BASF Corporation	OLD	
850.2300	Avian reproduction - duck	44457728	BASF Corporation	OLD	
850.1075	Freshwater fish LC50 - cold water species (TGAI)	44457730	BASF Corporation	OLD	
850.1075	Freshwater fish LC50 - warm water species (TGAI)	44457729	BASF Corporation	OLD	
850.1010	Freshwater invertebrate LC50 - (TGAI)	44457731	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - fish (TGAI)	44457732	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - mollusk (TGAI)	44457733	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - shrimp (TGAI)	44457734	BASF Corporation	OLD	
850.1300	Aquatic invertebrate life cycle - freshwater	CITE-ALL	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF.
850.1400	Fish early life stage - freshwater	CITE-ALL	BASF Corporation	PAY	
850.3020	Honey bee acute contact LD50	44457781	BASF Corporation	OLD	
850.4100	Seedling emergence, Tier I	CITE-ALL	BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF.
850.4150	Vegetative vigor, Tier I	CITE-ALL	BASF Corporation	PAY	
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient: Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF
			BASF Corporation	PAY	
			BASF Corporation	OLD	
BASF Corporation	PAY	Study required under Registration Review (ID # GDCI-112600-1313); not yet submitted to EPA by BASF			
BASF Corporation	PAY				
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400 850.5400	Aquatic plant growth, Tier I	44457776 44457777 44457778 44457779 44457780	BASF Corporation BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD OLD	
860.1300	Nature of residue - apple	44425216	BASF Corporation	OLD	
860.1300	Nature of residue - hen	44457794	BASF Corporation	OLD	
860.1300	Nature of residue - goat	44457801	BASF Corporation	OLD	
860.1300	Metabolism of (carbon 14) - Prohexadione Calcium in Peanut	44457793	BASF Corporation	OLD	
860.1340	Independent method validation - animal tissues, milk, and apple commodities	44457804	BASF Corporation	OLD	
860.1340	Residue analytical method - animal tissues (liver, kidney, fat, and muscle), milk, and apple commodities	44457805	BASF Corporation	OLD	
860.1340	Residue analytical method-plants	44725217	BASF Corporation	OLD	
860.1340	Independent method validation of Analytical Method for Peanuts	44457803	BASF Corporation	OLD	
860.1340	Method for Determination of Prohexadione Residues in Peanut RAC (Nutmeat and Hay), and Peanut Process Fractions (Meal and Animal Matrices)	44457806	BASF Corporation	OLD	
860.1340	Independent Laboratory Validation for the Determination of Prohexadione-Ca in Plant and Animal Matrices	48106702	BASF Corporation	PAY	
Signature <u>[Signature]</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Multiresidue method	44457802	BASF Corporation	OLD	
860.1380	Storage stability - apples	45067901	BASF Corporation	PAY	
860.1380	Storage stability - peanuts	44457807	BASF Corporation	OLD	
860.1380	Storage stability - peanuts	44725218	BASF Corporation	OLD	
860.1480	Magnitude of residue - cow	44457809	BASF Corporation	OLD	
860.1500	Magnitude of residue - apple	44725220	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanuts	44457808	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanut process fractions	44457810	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanuts	44725219	BASF Corporation	OLD	
860.1500	Magnitude of residues in cool season grasses grown for seed	45136201	K.I. Chemicals USA Inc.	PAY	
860.1500	Magnitude of residue in sweet cherry	48106703	BASF Corporation	PAY	
860.1520	Magnitude of residue - processed apple fractions	44725222	BASF Corporation	OLD	
	Magnitude of residue - overview	44725223	BASF Corporation	OLD	
860.1850	Confined rotational crop	44457792	BASF Corporation	OLD	
	Informative Summary: Toxicological Profile Aggregate Risk Assessment and Determination of Safety for Prohexadione Calcium Tolerances on Peanuts and Pome Fruit	44725224	BASF Corporation	OLD	
840.1100	Droplet size spectrum	CITE-ALL	Spray Drift Task Force	PAY	
840.1200	Drift field evaluation	CITE-ALL	Spray Drift Task Force	PAY	
Signature <u>[Signature]</u>			Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date <u>12/5/14</u>



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Ingredient Prohexadione calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			K.I. Chemicals USA Inc.	PAY	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			Spray Drift Task Force	PAY	
Spray Drift Task Force	PAY				
Signature <u>Frederick T. Smith</u>		Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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 Do not send the completed form to this address

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Fine Agrochemicals Ltd., Hill End House, Whittington, Worcester WR5 2RQ, UK Phone 011 44 1905 361800	EPA Registration Number/File Symbol 62097-
Active Ingredient(s) and/or representative test compounds(s) Prohexadione calcium (PC Code 112600)	Date 12/5/14
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food; terrestrial non-food	Product Name Kudos™ 27.5 WDG

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 12/5/14	Typed or Printed Name and Title Frederick T. Smith, Agent (SciReg, Inc.)
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date <u>12/5/14</u>	EPA Reg No /File Symbol	62097-	Page	1	of	2
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Kudos™ 27.5 WDG				
Ingredient Prohexadione-calcium						
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
830.1550	Product identity and composition	49298801	Fine Agrochemicals Ltd.	OWN		
830.1600	Desc. of mat. used to produce the product	49298801	Fine Agrochemicals Ltd.	OWN		
830.1650	Desc. of formulation process	49298801	Fine Agrochemicals Ltd.	OWN		
830.1670	Discussion of formation of impurities	49298801	Fine Agrochemicals Ltd.	OWN		
830.1750	Certified limits	49298801	Fine Agrochemicals Ltd.	OWN		
830.1800	Enforcement analytical method	49298402	Fine Agrochemicals Ltd.	OWN		
830.6302-830.7520	Physical-chemical properties summary	49298802	Fine Agrochemicals Ltd.	OWN		
830.6302	Color	49298803	Fine Agrochemicals Ltd.	OWN		
830.6303	Physical state	49298803	Fine Agrochemicals Ltd.	OWN		
830.6304	Odor	49298803	Fine Agrochemicals Ltd.	OWN		
830.6314	Oxidation/reduction	49298803	Fine Agrochemicals Ltd.	OWN		
830.7000	pH	49298803	Fine Agrochemicals Ltd.	OWN		
830.7300	Density	49298803	Fine Agrochemicals Ltd.	OWN		
830.7520	Particle size distribution	49298803	Fine Agrochemicals Ltd.	OWN		
Signature <u>Frederick T. Smith</u>			Name and Title Frederick T. Smith, Agent (SciReg, Inc.)		Date <u>12/5/14</u>	



Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Date <u>12/5/14</u>	EPA Reg No /Fife Symbol	62097-	Page 1 of 2
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR15 2RQ United Kingdom	Product Kudos™ 27.5 WDG		

[illegible]

John T. Little

Name and Title
Frederick T. Smith, Agent (SciReg, Inc.)

Date 12/5/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date <u>12/5/14</u>	EPA Reg No /File Symbol <u>62097-</u>	Page <u>2</u> of <u>2</u>
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Kudos™ 27.5 WDG	

Ingredient Prohexadione calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity	49298804	Fine Agrochemicals Ltd.	OWN	
870.1200	Acute dermal toxicity	49298805	Fine Agrochemicals Ltd.	OWN	
870.1300	Acute inhalation toxicity	49298806	Fine Agrochemicals Ltd.	OWN	
870.2400	Primary eye irritation	49298807	Fine Agrochemicals Ltd.	OWN	
870.2500	Primary dermal irritation	49298808	Fine Agrochemicals Ltd.	OWN	
870.2600	Dermal sensitization	49298809	Fine Agrochemicals Ltd.	OWN	

Signature <u>Frederick T. Smith</u>	Name and Title Frederick T. Smith, Agent (SciReg, Inc.)	Date <u>12/5/14</u>
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Date <u>12/5/14</u>	EPA Reg No /File Symbol	62097-	Page 2 of 2
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Kudos™ 27.5 WDG		

[illegible]

Date
12/5/14



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D418683; **FILE SYMBOL No.:** 62097-UR (screen); **PRODUCT NAME:** Kudos 27.5 WDG; **DECISION No.:** 487225; **PC Code(s):** 112600; **ACTION CODE:** R334; **FOOD Use:** Yes

DATE OUT: April 1, 2014, 2014

SUBJECT: Completeness check screening for end use product "Kudos 27.5 WDG"

FROM: Shyam Mathur,
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

TO: Rosemary Kearns / Tony Kish, RM 22
Fungicide Branch / RD (7505P)

Company Name: Fine Agrochemicals Ltd.
Formulation Type: Herbicide
Active Ingredient(s): Prohexadione-calcium (27.5%)

MRID No(s): 492988-01 to 492988-03

CONCLUSION:

Group A: All Data submitted.

NOTE 1: Unregistered source of active ingredient (separate registration application submitted with FSN: 62097-UE; DP418727)
Claimed similarity to Reg. no. 7969-188

Group B: Data submitted

CSF: Basic CSF (01-15-2014) submitted

Kearns, Rosemary

From: Mathur, Shyam
Sent: Tuesday, April 01, 2014 4:06 PM
To: Kearns, Rosemary; Kish, Tony
Subject: 45/90 day screen for 62097-UE & 62097-UR
Attachments: 62097-UE (screen).doc; 62097-UR (screen).doc

Please find attached the results of 45/90 day screen for the products 62097-UE & 62097-UR. Thanks.

shyam

Shyam Mathur, Ph.D
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)
OCSPP/Environmental Protection Agency, USA
Tel: 703-308-9374
mathur.shyam@epa.gov

Kearns, Rosemary

From: Rate, Debra
Sent: Monday, December 08, 2014 2:01 PM
To: Kearns, Rosemary
Cc: Kish, Tony; Redden, John
Subject: Product Chemistry for 62097-UE

Rose-

I have the completeness screen that was done by Shyam (04-01-14) for this product (62097-UE). Shyam notes that the production process is not acceptable and that the registrant must submit a more detailed description of the process.

Do you have this information from the registrant?

Debra

Debra Rate, PhD
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division
7505P

Phone: 703-306-0309

SciReg, Inc.
Science and Regulatory Consultants

49298800

January 15, 2014

Mr. Tony Kish
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application
- Kudos™ 27.5 WDG
- Fine Agrochemicals, Ltd.

Dear Mr. Kish:

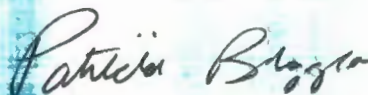
On behalf of Fine Agrochemicals Ltd. (FAL), SciReg, Inc. is submitting a me-too product registration application for Kudos™ 27.5 WDG, which contains 27.5% Prohexadione-Calcium (PC Code 112600).

Kudos™ 27.5 WDG is substantially similar in formulation and use to Apogee Plant Growth Regulator (EPA Reg. No. 7969-188). In support of this application, FAL is submitting product-specific product chemistry data and acute toxicity data.

This regulatory action falls under PRIA Category R334.2 – New product; MUP or end-use product with **unregistered source of the active ingredient**. This registration application is being submitted **concurrently with the technical registration application for Prohexadione Calcium Technical**. The corresponding PRIA fee is \$2,524, after Fine's 50% reduction. Enclosed, please find a receipt of payment and a PRIA certification statement.

If you have any questions regarding the application materials, please contact me at (703) 494-6500 or pbiggio@SciReg.com.

Sincerely,



Patricia Biggio
Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg, Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

Product Registration:
Kudos™ 27.5 WDG

Transmittal Date

January 15, 2014

Contents

Volume 1	Administrative Materials
49298801 Volume 2	Product Identity and Composition, Description of Beginning Materials, Description of Formulation Process, Discussion of the Formation of Impurities, and Certified Limits (OPPTS 830.1550, 830.1600, 830.1650, 830.1670, and 830.1750)
49298802 Volume 3	Physical and Chemistry Characteristics Summary (OPPTS 830.6302 – 830.7950)
49298803 Volume 4	Physical and Chemistry Characteristics: Color, Physical State, Odor, Chemical Incompatibility, pH, Density, Particle Size Distribution, and Dust Content (OPPTS 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, 830.7300 and 830.7520)
49298804 Volume 5	Acute Oral Toxicity (OPPTS 870.1100)
49298805 Volume 6	Acute Dermal Toxicity (OPPTS 870.1200)
49298806 Volume 7	Acute Inhalation Toxicity Waiver Request (OPPTS 870.1300)
49298807 Volume 8	Primary Eye Irritation (OPPTS 870.2400)
49298808 Volume 9	Primary Dermal Irritation (OPPTS 870.2500)

TRANSMITTAL DOCUMENT

49298809 Volume 10 Local Lymph Node Assay in the Mouse (OPPTS 870.2600)

December 24, 2013

Ms. Rose Kearns
Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Dr.
Arlington, VA 22202-4501

Re: Preregistration Meeting Minutes – Prohexadione-calcium
- Fine Agrochemicals Ltd. (Co. No. 62097)

Dear Ms. Kearns:

On behalf of Fine Agrochemicals Ltd., attached please find minutes from our December 11, 2013 preregistration meeting regarding prohexadione-calcium, as well as the following documents.

- Agenda
- Proposed data requirements table
- Manufacturing process for the technical product

Please review the minutes and let us know if the Agency has any comments or agrees with our version, as presented.

Should you have any questions, please let us know.

Sincerely,



Frederick T. Smith
Senior Regulatory Specialist

Enclosures

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 62097-UE/Prohexadione Calcium Technical
DP Barcode: 418356
PC Code: 112600

From: Maria Rivera Piansay, Chemist
Product Chemistry Team
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

Maria Rivera Piansay
ME

3/6/14

To: Tony Kish, PM 22
Fungicide Branch
Registration Division (7505P)

Applicant: Fine Agrochemicals, Ltd.
Hill End House, Whittington
Worcester, WR5 2RQ, UK

FORMULATION FROM EPA Reg. No. 62097-UE LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Prohexadione Calcium:	94.44%
<u>Inert Ingredient(s):</u>	5.56%
Total	100.00%

BACKGROUND:

The registrant is claiming similarity to EPA Reg. No. 7969-190 to support the registration of their new product, EPA Reg. No. 62097-UE. The MRID's listed in the data matrix are as follows: 444577-42 (81-1), 444577-43 (81-2), 444577-44 (81-3), 444577-45 (81-4), 444577-46 (81-5), 444577-47 (81-6). These studies have been reviewed and found to be acceptable to support the registration of the cited product.

After reviewing the studies, the CSFs, and the product tested in the studies, the EPA will allow the registrant to cite the studies listed above to support the registration of EPA Reg. No. 62097-UE.

The subject product will be assigned the following toxicity categories: acute oral (81-1) – IV; acute dermal (81-2) – III; acute inhalation (81-3) – IV; primary eye irritation (81-4) – IV; primary skin irritation (81-5) – IV; and will be classified as a non sensitizer

The registrant has submitted product chemistry data for review. These studies should go to TRB/RD for a full review.

RECOMMENDATIONS:

- The subject product will be assigned the toxicity categories listed above.
- The subject product will also be classified as a non-sensitizer.

The acute toxicity profile for EPA Reg. No. 62097-UE is currently:

Acute Oral	IV
Acute Dermal	III
Acute Inhalation	IV
Primary Eye	IV
Primary Dermal	IV
Skin sensitization	non-sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.

LABELING:

ID #: 062097-UE PROHEXADIONE CALCIUM TECHNICAL

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wear long sleeved shirt, long pants, shoes and socks, chemical resistant gloves (such as or made out of any waterproof material, selection category A).

FIRST AID:

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

21-Day Screen Completed by
Contractor

21-Day Expires on 2-5-14

Jacket # 62097-UE
MRID# 492984

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAEFER

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 1-15-14

Experts In-Processing Signature: B.B. Date 1-31-14 Fee Paid: Yes ☐

Division management contacted on issues No ☐ Yes ☐ Date

EPA Reg. Number: <u>62097-UE</u>		EPA Receipt Date: <u>1-15-14</u>					
Items for Review					Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type				X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)				X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no				
	<i>** NO inerts to review</i>						
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X		
	Certificate and data matrix consistent				X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no				
	If applicable, is there a letter of Authorization for exclusive use only.						
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)						X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X		
5	a) Selective Method (Fee category experts use)	X	no				
	b) Cite-All (Fee category experts use)						
	c) Applicant owns all data (Fee category experts use)						
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)				X		
7	Is the data package consistent with PR Notice 86-5				X		
8	Notice of Filing included with petitions						X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

- *Submitted studies PASSED PRN 11-3 review
- * Technical + impurities only, no merits to review
- * Jacket PASSED

JK

MRID: 492984

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 31, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-487223
EPA File Symbol or Registration Number: 62097-UE
Product Name: PROHEXADIONE CALCIUM TECHNICAL
EPA Receipt Date: 15-Jan-2014
EPA Company Number: 62097
Company Name: FINE AGROCHEMICALS, LTD

PATRICIA BIGGIO
SCIREG, INC.
FINE AGROCHEMICALS, LTD
12733 DIRECTOR'S LOOP
WOODBIDGE, VA 22192-

SUBJECT: Receipt of Application and 50% Small Business Waiver Request

Dear Registrant:

The Office of Pesticide Programs has received your application, 50% small business waiver request, and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R334
NEW PRODUCT:MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE
INGREDIENT:REQUIRES SCIENCE DATA REVIEW:NEW PHYSICAL FORM:SELECTIVE DATA CITATION:

Your request for waiver has been forwarded for review. You will be notified in writing when a determination is made regarding your request. If your waiver request is approved, the decision review time period will start on the date of approval. If your waiver request is denied, you will receive an invoice for the outstanding balance. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in black ink, appearing to be "m. j. z.", is written over the word "Sincerely,".

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{9462839~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☒ Fee Waiver?

☐ volpay % Reduction: 50

for Division

☐ AD

☐ BPPD

☐ RD

Risk Mgr. 22

Receipt No.

S- 946283

EPA File Symbol/Reg. No.

62097-UE

Pin-Punch Date:

1/15/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R334

Granted: R334

Amount Due: \$ 18,893

Parent/Child Decisions:

62097-UE

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Steve A. Aibile

Date: 1/20/14

Remarks:

Similarity Clinic

Receipt for Section 3

S: 946283

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Company: 62097 FINE AGROCHEMICALS, LTD

Billable: ☒ Yes ☐ No

Tracking



Risk Manager: Registration Division, Risk Management Team 22

Product #: 62097-UE

Product Name: PROHEXADIONE CALCIUM TECHNICAL

Override#:

Me Too

Section3: 7969-190

Me Too

Product Name: K-I CHEMICAL PROHEXADIONE CALCIUM MAI

Application Date: 15-Jan-2014

OPP Rec'd Date: 15-Jan-2014

Front End Date: 16-Jan-2014

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Initial application for registration

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Study

CSF

View/Edit



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 62097-	2. EPA Product Manager T. Kish	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Prohexadione Calcium Technical	PM# 22	
5. Name and Address of Applicant (Include ZIP Code) Fine Agrochemicals Ltd. Hill End House Whittington, Worcester WR5 2RQ UK <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 7969-190 Product Name K-I CHEMICAL PROHEXADIONE CALCIUM MANUFACTURING USE PRODUCT	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Initial application for registration.

PRIA Category: R334

PRIA Fee: \$18,893 (\$9,446.50 after 50% reduction)

Contact: pbiggio@SciReg.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt.	No. Per Container	If "Yes" Package wgt.	<input type="checkbox"/> Plastic	
			No. Per Container	<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) Bag and fiber drum	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 55 lbs (25kgs)		5. Location of Label Directions <input checked="" type="checkbox"/> On label. <input type="checkbox"/> On label accompanying product.	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Patricia Biggio		Title Agent	
		Telephone No. (Include Area Code) 703/494-6500	
Certification I certify that the statements which I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent (SciReg, Inc.)	
4. Typed Name Patricia Biggio		5. Date 15 Jan 2014	

Fred Smith

From: Martin Pritchard [martinp@fine.eu]
Sent: Tuesday, January 07, 2014 10:56 AM
To: Fred Smith
Cc: Iain Watt
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

Hi Fred,

Receipt for the Prohexadione calcium submission below. Kudos submission fee to follow.

Martin

Martin Pritchard
Director of Finance & Administration
Fine Agrochemicals Ltd
Tel: +44 1905 361800
Fax: +44 1905 361810
Direct: +44 1905 361814
martinp@fine.eu

The contents of this email and any attachments are strictly confidential and are intended solely for the attention and use of the named addressee(s). If you are not the addressee(s), you are not authorised to, and must not disclose, copy, distribute or retain this message without our prior written authority. If received in error, please notify the sender immediately or contact Fine Agrochemicals on the above number.

Please note that any views or opinions expressed in this email are solely those of the author and do not necessarily represent those of Fine Agrochemicals Limited.

-----Original Message-----

From: paygovadmin@mail.doc.twai.gov [mailto:paygovadmin@mail.doc.twai.gov]
Sent: 07 January 2014 15:55
To: Martin Pritchard
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at pay.gov.clev@clev.frb.org.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25DR1UVB
Agency Tracking ID: 74553326572
Transaction Type: Sale
Transaction Date: Jan 7, 2014 10:52:17 AM

Account Holder Name: Martin Pritchard
Transaction Amount: \$9,446.50
Billing Address: [REDACTED]
Billing Address 2: [REDACTED]
City: [REDACTED]
Zip/Postal Code: [REDACTED]
Country: GBR
Card Type: Visa
Card Number: *****1280

Decision Number:
Registration Number: Prohexadione calcium Company Name: Fine Agrochemicals Ltd Company Number: 62097 Action Code: R334

08 January 2014

To whom it may Concern

I, Julian Ward, the Managing Director of Fine Agrochemicals Ltd. am authorized and have personal knowledge sufficient to make this certification on behalf of Fine Agrochemicals Ltd. I hereby certify under penalty of perjury that, since a fee reduction request of 5 April 2013, there has been no change in the number of Fine Agrochemicals Ltd.'s employees, entities affiliated with Fine Agrochemicals Ltd. or average gross global revenue from pesticides, including any such revenue from affiliates and that the documentation submitted in connection with the request of 5 April 2013 remains true, complete, and correct and remains valid.

Yours sincerely,



Julian Ward
Managing Director
Fine Agrochemicals Ltd.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Fine Agrochemicals Ltd., Hill End House, Whittington, Worcester WR5 2RQ, UK Phone 011 44 1905 361800	EPA Registration Number/File Suffix 62097-
Active Ingredient(s) and/or representative test compounds(s) prohexadione-calcium	Date 15 Jan 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food; terrestrial non-food	Product Name Prohexadione Calcium Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Patricia Biggio</i>	Date 15 Jan 2014	Typed or Printed Name and Title Patricia Biggio, Agent (SciReg, Inc.)
-------------------------------------	---------------------	--

January 15, 2014

Mr. Tony Kish
Document Processing Desk (APPL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: New Product Registration Application
- Prohexadione Calcium Technical
- Fine Agrochemicals Ltd.

Dear Mr. Kish:

On behalf of Fine Agrochemicals Ltd., SciReg, Inc. is submitting a new product registration application for Prohexadione Calcium Technical (PC Code 112600). Prohexadione Calcium Technical is substantially similar to BASF's K-I Chemical Prohexadione Calcium Manufacturing Use Product (EPA Reg. No. 7969-190).

In support of this application, Fine is submitting its own Group A product chemistry and various waiver requests, and citing existing prohexadione-calcium data.

This regulatory action falls under PRIA Category R333 – New manufacturing-use product; registered active ingredient; selective data citation. The corresponding PRIA fee is \$18,893 (\$9,446.50 after Fine's 50% fee reduction). Enclosed, please find a receipt of payment and a PRIA certification statement.

If you have any questions regarding the application materials, please contact me at (703) 494-6500.

Sincerely,



Patricia Biggio
Regulatory Specialist

Enclosures

TRANSMITTAL DOCUMENT

Submitter

Fine Agrochemicals Ltd.
Hill End House
Whittington
Worcester WR5 2RQ
United Kingdom

SciReg, Inc.*
12733 Director's Loop
Woodbridge, VA 22192

*SciReg, Inc. is the authorized agent for Fine Agrochemicals Ltd.

Regulatory action in support of which this package is submitted

Product Registration:
Prohexadione Calcium Technical

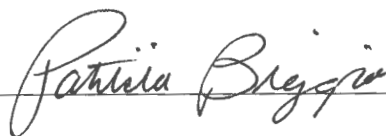
Transmittal Date

January 15, 2014

Contents

- | | |
|----------|---|
| Volume 1 | Administrative Materials |
| Volume 2 | Product Identity and Composition, Description of Beginning Materials, Description of Production Process, Discussion of the Formation of Impurities, and Certified Limits (OPPTS 830.1550, 830.1600, 830.1620, 830.1670, and 830.1750) |
| Volume 3 | Preliminary Analysis and Analytical Method (OPPTS 830.1700 and 830.1800) |
| Volume 4 | Prohexadione Calcium Technical: Immunotoxicity Waiver Request (OPPTS 870.7800) |
| Volume 5 | Prohexadione Calcium Technical: Toxicology, Terrestrial and Aquatic Nontarget Organism, Environmental Fate, and Post-Application Exposure Waiver Requests (OPPTS 835.4200, 835.4300, 850.1010, 870.3200 and 875.2200) |

Company Official: Patricia Biggio



Company Name: SciReg, Inc.

Company Contact: Patricia Biggio (703) 494-6500



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date <i>15 Jan 2014</i>		EPA Reg No./File Symbol	62097-	Page 1 of 7	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product identity and composition		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1600	Desc. of mat. used to produce the product		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1620	Desc. of production process		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1670	Discussion of formation of impurities		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1700	Preliminary analysis		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1750	Certified limits		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.1800	Enforcement analytical method		Fine Agrochemicals Ltd.	OWN	Submitted herein
830.6302	Color	44457704	BASF Corporation	OLD	
830.6303	Physical state	44457705	BASF Corporation	OLD	
830.6304	Odor	44457706	BASF Corporation	OLD	
830.6313	Stability	44457716	BASF Corporation	OLD	
830.6314	Oxidation/reduction	44457717	BASF Corporation	OLD	
830.6316	Explosibility	44457717	BASF Corporation	OLD	
830.7000	pH	44457715	BASF Corporation	OLD	
830.7200	Melting point	44457707	BASF Corporation	OLD	
830.7300	Density	44457708	BASF Corporation	OLD	
830.7370	Dissociation constant	44457713	BASF Corporation	OLD	
830.7550	Octanol/water partition coefficient	44457714	BASF Corporation	OLD	
830.7840	Solubility	44457709	BASF Corporation	OLD	
		44457710	BASF Corporation	OLD	
		44457711	BASF Corporation	OLD	
830.7950	Vapor Pressure	44457712	BASF Corporation	OLD	
Signature <i>Patricia Biggio</i>			Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date <i>15 Jan 2014</i>



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Date <i>15 Jan 2014</i>			EPA Reg No./File Symbol	62097-	Page 2 of 7
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom			Product Prohexadione Calcium Technical		
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute oral toxicity	44457742	BASF Corporation	OLD	
870.1200	Acute dermal toxicity	44457743	BASF Corporation	OLD	
870.1300	Acute inhalation toxicity	44457744	BASF Corporation	OLD	
870.2400	Primary eye irritation	44457745	BASF Corporation	OLD	
870.2500	Primary dermal irritation	44457746	BASF Corporation	OLD	
870.2600	Dermal sensitization	44457747	BASF Corporation	OLD	
870.6100	Acute neurotoxicity - rat	44457748	BASF Corporation	OLD	
870.6200	90-Day neurotoxicity - rat	44457753	BASF Corporation	OLD	
870.3100	90-Day Oral - rodent	44457749	BASF Corporation	OLD	
		44457750	BASF Corporation	OLD	
		44499902	BASF Corporation	OLD	
870.3150	90-Day Oral - non-rodent	44457751	BASF Corporation	OLD	
		44457752	BASF Corporation	OLD	
870.3200	21/28-day dermal TGA1	45430301	BASF Corporation	PAY	
870.4100	Chronic - rodent	44457754	BASF Corporation	OLD	
870.4100	Chronic - non-rodent	44457751	BASF Corporation	OLD	
		44457755	BASF Corporation	OLD	
870.4200	Oncogenicity - rat	44457754	BASF Corporation	OLD	
870.4200	Oncogenicity - mice	44457756	BASF Corporation	OLD	
870.3700	Developmental toxicity - rat	44457757	BASF Corporation	OLD	
		44457758	BASF Corporation	OLD	
870.3700	Developmental toxicity - rabbit	44457759	BASF Corporation	OLD	
		44457760	BASF Corporation	OLD	
		44457761	BASF Corporation	OLD	
		44457762	BASF Corporation	OLD	
870.3800	Reproduction, 2-generation	44457763	BASF Corporation	OLD	
		44457764	BASF Corporation	OLD	
870.5100	Bacterial reverse mutation assay	44457765	BASF Corporation	OLD	
Signature <i>Patricia Biggio</i>			Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date <i>15 JAN 2014</i>



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DATA MATRIX

Date 15 JAN 2014

EPA Reg No./File Symbol 62097-

Page 3 of 7

Applicant's/Registrant's Name & Address

Fine Agrochemicals Ltd.
Hill End House, Whittington
Worcester WR5 2RQ
United Kingdom

Product

Prohexadione-Calcium Technical

Ingredient Prohexadione-Calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5300 870.5375	<i>In vitro</i> mammalian cell assay	44457768 44499903 44499904	BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD	
870.5385 870.5395	<i>In vivo</i> cytogenetics	44457767 44457769	BASF Corporation BASF Corporation	OLD OLD	
870.7485	Metabolism and pharmacokinetics	44457770 44457771 44457772 44457773	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
870.7800	Immunotoxicity		Fine Agrochemicals Ltd.	OWN	Submitted herein
875.1100	Dermal outdoor exposure	CITE-ALL	Agricultural Handler Exposure (AHETF) Agricultural Reentry Task Force (ARTF) Outdoor Residential Exposure Task Force (ORETF)	PER PER PER	
875.1300	Inhalation outdoor exposure	CITE-ALL	AHETF ARTF ORETF	PER PER PER	
875.1600	Data reporting and calculations	CITE-ALL	AHETF ARTF ORETF	PER PER PER	
875.2100	Disloc'geable foliar residue			GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
875.2400	Dermal exposure	CITE-ALL	ARTF	PER	
875.2500	Inhalation exposure	CITE-ALL	ARTF	PER	

Signature

Patricia Biggio

Name and Title

Patricia Biggio, Agent (SciReg, Inc.)

Date

15 JAN 2014 150



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date 15 JAN 2014		EPA Reg No./File Symbol 62097-		Page 4 of 7	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione-Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Informative Summary: Toxicological Profile, Aggregate Risk Assessment and Determination of Safety for Prohexadione Calcium Tolerances on Peanuts	44457811	BASF Corporation	OLD	
835.2120	Hydrolysis	44457782	BASF Corporation	OLD	
835.2240	Photodegradation in water	44457783	BASF Corporation	OLD	
835.2410	Photodegradation in soil	44457784	BASF Corporation	OLD	
835.4100	Aerobic soil metabolism	44457785	BASF Corporation	OLD	
835.4400	Anaerobic aquatic metabolism	44457786	BASF Corporation	OLD	
835.1230 835.1240	Leaching/adsorption/desorption	44457787 44457788 44457789 44457790	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
835.6100	Terrestrial field dissipation	44457791 44725213 44725214 44725215	BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD	
Signature <i>Patricia Biggio</i>			Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date 15 JAN 2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date	15 JAN 2014	EPA Reg No./File Symbol	62097-	Page	5 of 7
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2100	Avian acute oral - passerine			GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
850.2100	Avian acute oral - quail or duck	44457723 44457724	BASF Corporation BASF Corporation	OLD OLD	
850.2200	Avian dietary toxicity - quail	44457725	BASF Corporation	OLD	
850.2200	Avian dietary toxicity - duck	44457726	BASF Corporation	OLD	
850.2300	Avian reproduction - quail	44457727	BASF Corporation	OLD	
850.2300	Avian reproduction - duck	44457728	BASF Corporation	OLD	
850.1075	Freshwater fish LC50 - cold water species (TGAI)	44457730	BASF Corporation	OLD	
850.1075	Freshwater fish LC50 - warm water species (TGAI)	44457729	BASF Corporation	OLD	
850.1010	Freshwater invertebrate LC50 - (TGAI)	44457731	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - fish (TGAI)	44457732	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - mollusk (TGAI)	44457733	BASF Corporation	OLD	
850.1025	Estuarine and marine toxicity - shrimp (TGAI)	44457734	BASF Corporation	OLD	
850.1300	Aquatic invertebrate life cycle - freshwater			GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
850.1400	Fish early life stage - freshwater			GAP	
850.3020	Honey bee acute contact LD50	44457781	BASF Corporation	OLD	
850.4100	Seedling emergence, Tier I			GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
850.4150	Vegetative vigor, Tier I			GAP	
Signature Patricia Biggio		Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date 15 JAN 2014	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

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DATA MATRIX

Date 15 JAN 2014	EPA Reg No./File Symbol 62097-	Page 6 of 7			
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400 850.5400	Aquatic plant growth, Tier I	44457776 44457777 44457778 44457779 44457780	BASF Corporation BASF Corporation BASF Corporation BASF Corporation BASF Corporation	OLD OLD OLD OLD OLD	
860.1300	Nature of residue - apple	44425216	BASF Corporation	OLD	
860.1300	Nature of residue - hen	44457794	BASF Corporation	OLD	
860.1300	Nature of residue - goat	44457801	BASF Corporation	OLD	
860.1300	Metabolism of (carbon 14) - Prohexadione Calcium in Peanut	44457793	BASF Corporation	OLD	
860.1340	Independent method validation - animal tissues, milk, and apple commodities	44457804	BASF Corporation	OLD	
860.1340	Residue analytical method - animal tissues (liver, kidney, fat, and muscle), milk, and apple commodities	44457805	BASF Corporation	OLD	
860.1340	Residue analytical method-plants	44725217	BASF Corporation	OLD	
860.1340	Independent method validation of Analytical Method for Peanuts	44457803	BASF Corporation	OLD	
860.1340	Method for Determination of Prohexadione Residues in Peanut RAC (Nutmeat and Hay), and Peanut Process Fractions (Meal and Animal Matrices)	44457806	BASF Corporation	OLD	
860.1340	Independent Laboratory Validation for the Determination of Prohexadione-Ca in Plant and Animal Matrices	48106702	BASF Corporation	PAY	
Signature Patricia Biggio			Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date 15 JAN 2014



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DATA MATRIX

Date 15 JAN 2014	EPA Reg No./File Symbol 62097-	Page 7 of 7			
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
860.1360	Multiresidue method	44457802	BASF Corporation	OLD	
860.1380	Storage stability - apples	45067901	BASF Corporation	PAY	
860.1380	Storage stability - peanuts	44457807	BASF Corporation	OLD	
860.1380	Storage stability - peanuts	44725218	BASF Corporation	OLD	
860.1480	Magnitude of residue - cow	44457809	BASF Corporation	OLD	
860.1500	Magnitude of residue - apple	44725220	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanuts	44457808	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanut process fractions	44457810	BASF Corporation	OLD	
860.1500	Magnitude of residue - peanuts	44725219	BASF Corporation	OLD	
860.1500	Magnitude of residues in cool season grasses grown for seed	45136201	K.I. Chemicals USA Inc.	PAY	
860.1500	Magnitude of residue in sweet cherry	48106703	BASF Corporation	PAY	
860.1520	Magnitude of residue - processed apple fractions	44725222	BASF Corporation	OLD	
	Magnitude of residue - overview	44725223	BASF Corporation	OLD	
860.1850	Confined rotational crop	44457792	BASF Corporation	OLD	
	Informative Summary: Toxicological Profile Aggregate Risk Assessment and Determination of Safety for Prohexadione Calcium Tolerances on Peanuts and Pome Fruit	44725224	BASF Corporation	OLD	
840.1100	Drift size spectrum	CITE-ALL	Spray Drift Task Force	PAY	
840.1200	Drift field evaluation	CITE-ALL	Spray Drift Task Force	PAY	
Signature Patricia Biggio			Name and Title Patricia Biggio, Agent (SciReg, Inc.)	Date 15 JAN 2014	



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Date <i>15 JAN 2014</i>		EPA Reg No./File Symbol	62097-	Page 1 of 7	
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			Signature <i>Patricia Biggio</i>		



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DATA MATRIX

Date <i>15 Jan 2014</i>	EPA Reg No./File Symbol 62097-	Page 2 of 7
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Prohexadione Calcium Technical	

Ingredient Prohexadione-Calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	

Signature <i>Patricia Biggio</i>	Name and Title Patricia Biggio, Agent (SciReg, Inc.)	Date <i>15 Jan 2014</i>
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DATA MATRIX

Date 15 JAN 2014	EPA Reg No./File Symbol 62097-	Page 3 of 7
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Prohexadione-Calcium Technical	

Ingredient Prohexadione-Calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			EiASF Corporation	OLD	
			EiASF Corporation	OLD	
			EiASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			Fine Agrochemicals Ltd.	OWN	Submitted herein
			Agricultural Handler Exposure (AHETF)	PER	
			Agricultural Reentry Task Force (ARTF)	PER	
			Outdoor Residential Exposure Task Force (ORETF)	PER	
			AHETF	PER	
			ARTF	PER	
			ORETF	PER	
				GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
			ARTF	PER	
			ARTF	PER	

Signature

Patricia Biggie

Name and Title

Patricia Biggie, Agent (SciReg, Inc.)

Date

15 JAN 2014



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DATA MATRIX

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Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
Signature			Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date 15 JAN 2014



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Date	15 JAN 2014	EPA Reg No./File Symbol	62097-	Page	5 of 7
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
				GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
				GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
			BASF Corporation	OLD	
				GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA
			GAP	Study required under Registration Review; Fine will rely upon these data when submitted to EPA	
Signature		Name and Title		Date	
Patricia Biggio		Patricia Biggio, Agent (SciReg, Inc.)		15 JAN 2014	



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Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom		Product Prohexadione Calcium Technical			
Ingredient Prohexadione-Calcium					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	PAY	
Signature <i>Patricia Biggio</i>		Name and Title Patricia Biggio, Agent (SciReg, Inc.)		Date 15 JAN 2014	



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Date 15 JAN 2014	EPA Reg No./File Symbol 62097-	Page 7 of 7
Applicant's/Registrant's Name & Address Fine Agrochemicals Ltd. Hill End House, Whittington Worcester WR5 2RQ United Kingdom	Product Prohexadione Calcium Technical	

Ingredient Prohexadione-Calcium

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BASF Corporation	OLD	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			K.I. Chemicals USA Inc.	PAY	
			BASF Corporation	PAY	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			BASF Corporation	OLD	
			Spray Drift Task Force	PAY	
			Spray Drift Task Force	PAY	

Signature <i>Patricia Biggio</i>	Name and Title Patricia Biggio, Agent (SciReg, Inc.)	Date 15 JAN 2014
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Prohexadione Calcium Technical

Plant growth regulator for manufacturing use only

Active Ingredient: Prohexadione calcium [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate]..... 94.44%
Other Ingredients:..... 5.56%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg. No. 62097-

EPA Est. No.

Net Contents:
Batch No.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 (National Pesticide Information Center) for emergency medical treatment information, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulating end-use products for apples, grass grown for seed, peanuts and sweet cherry. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration of its end-use products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container only. After partial use, close the container tightly. Store in a secure place that is temperate and dry. Use spray and stock solutions within 24 hours. Immediate use is required if another component is added to the spray solution.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

[for container size 5 pounds or less] **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.]

[for container size greater than 50 pounds] **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.]

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

Fine Agrochemicals Limited ("FINE") warrants that this Product conforms to the specifications on this label. To the extent consistent with applicable law, FINE makes no other warranties and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for a particular purpose. No agent of FINE or any other person is authorized to make any representation or warranty beyond those contained herein.

It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as abnormal weather conditions, use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

To the extent consistent with applicable law: 1) FINE disclaims any liability whatsoever for special, incidental or consequential damages resulting from the handling or use of this Product and 2) FINE's liability under this label shall be limited to the amount of the purchase price or, at the election of FINE, the free replacement of the Product.

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United Kingdom

Prohexadione Calcium Technical

Plant growth regulator for manufacturing use only

Active Ingredient: Prohexadione calcium [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate]..... 94.44%
Other Ingredients:..... 5.56%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg. No. 62097-

EPA Est. No.

Net Contents:
Batch No.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 (National Pesticide Information Center) for emergency medical treatment information, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulating end-use products for apples, grass grown for seed, peanuts and sweet cherry. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration of its end-use products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container only. After partial use, close the container tightly. Store in a secure place that is temperate and dry. Use spray and stock solutions within 24 hours. Immediate use is required if another component is added to the spray solution.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

[for container size 5 pounds or less] **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.]

[for container size greater than 50 pounds] **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.]

WARRANTY DISCLAIMER AND LIMITATION OF LIABILITY

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It is impossible to eliminate all risks associated with this Product. Plant injury, lack of performance, or other unintended consequences may result because of factors such as abnormal weather conditions, use of the Product other than in strict accordance with this label's instructions, presence of other materials, the manner of application or other factors, all of which are beyond the control of FINE or the seller. To the extent consistent with applicable law, all such risks shall be assumed by the Buyer.

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United Kingdom

Prohexadione Calcium Technical

Plant growth regulator for manufacturing use only

Active Ingredient: Prohexadione calcium [calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate]..... 94.44%
Other Ingredients:..... 5.56%
Total: 100.00%

KEEP OUT OF REACH OF CHILDREN CAUTION

EPA Reg. No. 62097-

EPA Est. No.

Net Contents:
Batch No.

FIRST AID	
IF IN EYES	<ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.• Call a poison control center or doctor for treatment advice.
IF ON SKIN OR CLOTHING	<ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15-20 minutes.• Call a poison control center or doctor for treatment advice.
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-858-7378 (National Pesticide Information Center) for emergency medical treatment information, 6:30 AM to 4:30 PM Pacific time (PT), seven days a week.	

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing.

ENVIRONMENTAL HAZARDS

For terrestrial uses. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters or rinsate.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is to be used only for formulating end-use products for apples, grass grown for seed, peanuts and sweet cherry. This product may also be used to formulate products for any additional uses not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s). Each formulator is responsible for obtaining EPA registration of its end-use products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container only. After partial use, close the container tightly. Store in a secure place that is temperate and dry. Use spray and stock solutions within 24 hours. Immediate use is required if another component is added to the spray solution.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

[for container size 5 pounds or less] **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.]

[for container size greater than 50 pounds] **CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container $\frac{1}{4}$ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling or reconditioning, if available, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.]

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